

**Data Evaluation Report on the Acute Toxicity of BAS 183 WB H (Dicamba) to Fish
(*Pimephales promelas*)**

PMRA Submission Number {.....}

EPA MRID Number 48718008

Data Requirement:

PMRA Data Code	{.....}
EPA DP Barcode	402518
OECD Data Point	{.....}
EPA MRID	48718008
EPA Guideline	850.1075

Test material: BAS 183 WB H

Purity: 48.41%

Common name: Dicamba

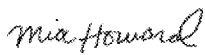
Chemical name: IUPAC

CAS name

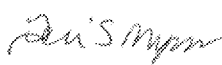
CAS No.

Synonyms: BAS 183 H LVF, BAAS 183 22 H, BAPMA Dicamba Salt

Primary Reviewer: Mia Howard
Environmental Scientist, CDM Smith

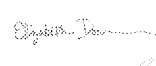
Signature: 
Date: 1/22/13

Secondary Reviewer: Teri S. Myers
Environmental Scientist, CDM Smith

Signature: 
Date: 1/24/13

Primary Reviewer: Elizabeth Donovan, Biologist
EPA/EFED/ERB 6

Date: 9/7/2016


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Date: 2016.11.09 07:10:17 -0500

Reference/Submission No.: {.....}

Company Code {.....} [For PMRA]
Active Code {.....} [For PMRA]
Use Site Category: {.....} [For PMRA]
EPA PC Code 100094

Date Evaluation Completed: 11-3-2016

CITATION: Salinas, E. 2011. BAS 183 WB H—Acute Toxicity in the Fathead Minnow (*Pimephales promelas*). Study performed by Experimental Toxicology and Ecology, BASF SE, Ludwigshafen, Germany. Study identification numbers: 19F0040/10E122 and 395298. Study sponsored by BASF Corporation. Study initiated 05 May 2011 and completed 05 August 2011.

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to fish. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

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EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, fathead minnow (*Pimephales promelas*) were exposed to BAS 183 WB H (Dicamba) at nominal concentrations of 0 (control) and 120 mg/L under static conditions. Mean measured concentrations were <LOD (control) and 119.4 mg formulation/L (57.8 mg ai/L). The 96-h LC₅₀ was >119.4 mg formulation/L (57.8 mg ai/L), based on mean measured concentrations. No mortality or sub-lethal toxicity symptoms were observed in either the control or test group. The NOAEC value, based on mortality/sub-lethal effects was 119.4 mg formulation/L (57.8 mg ai/L). Based on the results of this study, BAS 183 WB H would be classified as practically nontoxic to *Pimephales promelas* in accordance with the classification system of the U.S. EPA.

This toxicity study is classified scientifically sound and does satisfy the guideline requirement for an acute fish (*Pimephales promelas*) toxicity study.

Results Synopsis

Test Organism Size/Age(mean weight or length): ~2.5 months (age), 0.22 g (weight), 2.9 cm (length)

Test Type (Flow-through, Static, Static Renewal): Static

Results in terms of mean measured formulation concentrations

LC₅₀: >119.4 mg formulation/L 95% C.I.: N/A

NOAEC: 119.4 mg formulation/L Probit Slope: N/A

Endpoint(s) Affected: None

Results in terms of mean measured active ingredient (dicamba) concentrations

LC₅₀: >57.8 mg ai/L 95% C.I.: N/A

NOAEC: 57.8 mg ai/L Probit Slope: N/A

Endpoint(s) Affected: None

Results in terms of mean measured acid equivalent concentrations

LC₅₀: >56.4 mg ae/L 95% C.I.: N/A

NOAEC: 56.4 mg ae/L Probit Slope: N/A

Endpoint(s) Affected: None

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

The study was designed to comply with the following guidelines: (1) Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and the Council on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Part C.1: Methods for the Determination of Ecotoxicity: Acute Toxicity for Fish; Official Journal of the European Union, No. L 142; (2) OECD (1992), *Test No. 203: Fish, Acute Toxicity Test*, OECD Guidelines for the Testing of Chemicals, Section 2: Effects on Biotic Systems, No. 370, OECD Publishing; (3) EPA-Guideline "Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms", U.S. EPA, Washington D.C., 540/09-82-024, §72-1, Acute toxicity for freshwater fish (1982); (4) EPA Ecological Effects Test Guidelines, OPPTS 850.1075 (Public Draft, April 1996): Fish Acute Toxicity Test, Freshwater and Marine, EPA 712-C-96-118. The following deviations from the U.S. EPA OPPTS 850.1075 guideline are noted:

1. No lighting transition periods were reported. 15-30 minute transition periods are recommended.
2. The test water was slightly aerated during the last days of the test, due to a noted decline in dissolved oxygen concentration (69-74% of saturation) after 48 hours. The guideline states that if aeration is used, test concentrations must be measured during the test. Test concentrations were only verified at test initiation and termination, however, based on the measurements at these time points, the test substance was stable (only declined by 1%).
3. The particulate matter, total organic carbon, chlorine, metals, and pesticide concentrations of the dilution water were not reported. The study author noted that the tap water used to prepare the test water is regularly assayed for chemical contaminants both the municipal authorities of Frankenthal and by the Environmental Analytics Water/Steam Monitoring of BASF SE and for bacteria by a contract laboratory. The results of these analyses were not included in the report.

These deviations do not affect the validity of the study.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and No Data Confidentiality statements were provided. The study was conducted in compliance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz", which meet the U.S. Environmental Protection Agency GLP standards (40 CFR Part 160 (FIFRA) and Part 792 (TSCA)) with the exception that recognized differences exist between the GLP Principles/Standards of OECD and the Principles/Standards of FIFRA and TSCA.

A. MATERIALS:

1. Test material	BAS 183 WB H
Description:	Clear brown liquid
Lot No./Batch No. :	1732-10
Purity:	48.41%

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**Stability of compound
under test conditions:**

Stable. At test initiation, measured concentrations were 100% of nominal.
After 96 hours, measured concentrations were 99% of nominal.

(OECD recommends water solubility, stability in water and light, pKa, Pow, and vapor pressure of test compound)

**Storage conditions of
test chemicals:**

Ambient

Physicochemical properties of BAS 183 WB H.

Parameter	Values	Comments
Water solubility at 20EC	Dispersible in test water up to 100 mg/L	The temperature of the solubility observation at the ecotoxicology laboratory was not reported
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

2. Test organism:

Species:

Fathead minnow (*Pimephales promelas*) EPA recommends a cold water species (preferably rainbow trout *Oncorhynchus mykiss*) and a warm water species (preferably bluegill sunfish *Lepomis macrochirus*). OECD recommends choice of species at discretion of testing laboratory.

Age at test initiation:

Approximately 2.5 months

Weight at study initiation*:

Mean: 0.22 g, range: 0.15 to 0.32 g EPA recommends: mean 0.5 - 5 g.

Length at study initiation*:

Mean: 2.9 cm, range: 2.6 to 3.4 cm EPA recommends: Longest not > 2x shortest; OECD recommends 2.0 ∇ 1.0 cm for bluegill and 5.0 ∇ 1.0 cm for rainbow trout

*Measurements were made at test termination using all surviving fish

Source:

In-house cultures EPA recommends that all organisms be from the same source

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding study: In a preliminary test, a test concentration of 120 mg/L caused no mortality or sublethal effects after 96 hours.

b. Definitive Study

Table 1: Experimental Parameters

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Parameter	Details	Remarks
		Criteria
<u>Acclimation</u>		
Period:	At least 14 days	<i>The recommended acclimation period is a minimum of 14 days; OECD guideline recommends a minimum of 12 days. Pretest mortality should be < 3% 48 h. prior to testing. OECD pretest mortality criteria: >10% = rejection of entire batch; ≥ 5 and $\leq 10\%$ = continued acclimation for 7 days; <5% = acceptable.</i>
Conditions: (same as test or not)	Same as test	
Feeding:	Fed a commercial fish diet, Tetramin (Tetra-Werke, Melle, Germany) <i>ad libitum</i> , and juvenile brine shrimp (<i>Artemia nauplii</i>) generally on work days	
Health: (any mortality observed)	All test fish were reported to be healthy at test initiation, showing no signs of illness, injury, or abnormalities	
Duration of the test	96 hours	<i>The recommended test duration is 96 hours.</i>
<u>Test condition</u>		
Static/flow-through	Static	<i>A reproducible supply of toxicant is recommended. Consistent flow rate is usually 5-10 vol/24 hours; meter systems should be calibrated before and after study and checked twice daily during test period.</i>
Type of dilution system - for flow-through method.	N/A	
Renewal rate for static renewal	N/A	
Aeration, if any	No aeration was provided over the first 24 hours. Due to dissolved oxygen concentrations that had declined to 69-74% of saturation after 48 hours, slight aeration was provided during the last days of the test. The concentration of the test substance was not decreased by aeration.	<i>Aeration is not recommended; OECD guideline recommends aeration. If aeration is necessary, test solutions must be analyzed periodically to verify exposure.</i>

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Parameter	Details	Remarks
		Criteria
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	Glass 30 x 22 x 24 hours 10 L	Test vessel size is usually 19 L (5 gal) or 30 x 60 x 30 cm. Fill volume is usually 15-30 L of solution.
Source of dilution water Quality:	Non-chlorinated charcoal filtered tap water from Frankenthal, Germany	Recommended source of dilution water is soft, reconstituted water or water from a natural source. EPA does not recommend the use of dechlorinated tap water; however, its use may be supportable if the biological responses for the organisms and chemical analyses of residual chlorine meet conditions in the Agency's 850.1010 guidelines for dilution water (http://www.epa.gov/opptsfrs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Draft/850.1010.pdf) Dilution water should be intensely aerated before the study. OECD permits dechlorinated tap water.

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Parameter	Details	Remarks
		Criteria
<u>Water parameters:</u> Hardness	100 mg/L CaCO ₃	The study author noted that the tap water used to prepare the test water is regularly assayed for chemical contaminants both the municipal authorities of Frankenthal and by the Environmental Analytics Water/Steam Monitoring of BASF SE and for bacteria by a contract laboratory. The results of these analyses were not included in the report.
pH	7.9 to 8.1	
Dissolved oxygen	5.9 to 8.4 mg/L ($\geq 69\%$ of saturation)	
Total Organic carbon	Not reported	
Particulate Matter	Not reported	
Metals	Not reported	<u>Hardness:</u> EPA recommends 40 - 48 mg/L as CaCO ₃ (OECD recommends 10 - 250 mg/L) <u>pH:</u> EPA recommends 7.2 - 7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes, monthly range < 0.8; (OECD recommends pH 6.0 - 8.5) <u>Dissolved Oxygen:</u> EPA recommends: Static: $\geq 60\%$ during first 48 hrs and $\geq 40\%$ during second 48 hrs; flow-through: $\geq 60\%$; (OECD guideline recommends at least 80% saturation value). <u>Temperature:</u> EPA recommends 12 EC for coldwater species, 17 or 22 EC for warmwater species, and 22 ± 1 EC for estuarine/marine organisms. (OECD recommends 21 - 25°C for bluegill and 13 - 17°C for rainbow trout). <u>Salinity:</u> EPA recommends 30-34‰ (parts per thousand) for marine, 10-17‰ for estuarine fish, weekly range < 6‰. Water quality should be measured at beginning of test and every 48 hours.
Pesticides	Not reported	
Chlorine	Not reported	
Temperature	24°C	
{Salinity for marine or estuarine species}	N/A	
Intervals of water quality measurement	Temperature, dissolved oxygen content, and pH were measured in each test vessel within 1 hour of test initiation and after 24, 48, 72, and 96 hours of exposure	
<u>Number of replicates/groups:</u> control: solvent control: treated ones:	1 N/A 1	Recommended number of replicates include a control and five treatment levels. Each concentration should be 60% of the next highest concentration; concentrations should be in a geometric series.
Number of organisms per replicate		

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Parameter	Details	Remarks
		Criteria
<u>/groups:</u> control: solvent control: treated ones:	10 N/A 10	Number of organisms per replicate should be ≥ 10 /concentration; OECD guideline recommends at least 7 fish/concentration.
Biomass loading rate	0.22 g fish/L	Recommended static conditions are #0.8 g/L at #17EC and #0.5 g/L at > 17EC. Recommended flow-through conditions are #1 g/L/day. OECD recommends a maximum of 1 g fish/L for static and semi-static, while higher rates are recommended for flow-through.
<u>Test concentrations:</u> nominal: measured:	0 (control), 120 mg formulation/L <LOD (control), 119.4 mg formulation/L (57.8 mg ai/L)	
Solvent (type, percentage, if used)	N/A	The solvent should not exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD recommends that the solvent not exceed 100 mg/L.
Lighting	16 hours light, 8 hours dark, approximately 96-451 lux	No transition periods were noted The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period. OECD recommends a photo period of 12 -16 hours.
Feeding	Not fed during the test	Fish should not feed during the study.
<u>Recovery of chemical</u> Frequency of determination Level of quantization Level of detection	30 minutes prior to the start of exposure and at test termination (approximately 96 hours) Not reported Not reported	
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any	N/A	

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2. Observations:

Table 2: Observations

Parameter	Details	Remarks
		Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality Clinical signs of toxicity	
Observation intervals	1, 6, 24, 48, 72, and 96 hours	Observation intervals should be a minimum of every 24 hours.
Were raw data included?	Yes	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

After 96 hours, no mortalities were observed in the control or limit concentration group. Therefore, the NOAEC and LC₅₀ were determined to be 119.4 and >119.4 mg formulation/L, respectively, based on mean measured concentrations. *EPA/OECD require pretreatment control mortality < 10%.. EPA requires that control or solvent mortality not exceed 10%. OECD requires that maximum-allowable control or solvent control mortality is 10% (or 1 mortality if 7 to 10 control fish are used) for a 96-h period of testing.*

Table 3: Effect of BAS 183 WB H on Mortality of fathead minnow (*Pimephales promelas*)

Treatment (mg/L) Nominal (and mean measured) concentrations	No. of fish at start of study	Observation period					
		Day 1		Day 3		Day 4	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Control	10	0	0	0	0	0	0
120 (119.4)	10	0	0	0	0	0	0
NOAEC	120 mg formulation/L (nominal), 119.4 mg formulation/L (mean measured)						
LC ₅₀	>120 mg formulation/L (nominal), >119.4 mg formulation/L (mean measured)						
Positive control, if used mortality: LC ₅₀ :	N/A						

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B. NON-LETHAL TOXICITY ENDPOINTS:

No sub-lethal signs of toxicity or abnormalities were observed in the control or treatment group. Therefore the NOAEC based on sub-lethal effects was 119.4 mg formulation/L (57.8 mg ai/L), based on mean measured concentrations.

C. REPORTED STATISTICS:

Because the study was a limit test, no statistical analyses were performed.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Due to the lack of mortality, no statistical analyses were performed. The LC50 and NOAEC values were empirically determined to be greater than and equal to limit concentration, respectively. The toxicity values are reported in terms of mean measured concentrations.

LC₅₀: >119.4 mg formulation/L 95% C.I.: N/A

NOAEC: 119.4 mg formulation/L

Probit Slope: N/A 95% C.I.: N/A

E. STUDY DEFICIENCIES:

Deviations cited in Section I. Materials and Methods were considered to be minor. There were no study deficiencies.

F. REVIEWER'S COMMENTS:

All test solutions were visibly clear with no undissolved test material.

The in-life phase of the definitive test was conducted between 09 and 13 May 2011.

G. CONCLUSIONS:

This study is scientifically sound and is thus acceptable. No toxicity was observed in this test.

Results in terms of mean measured formulation concentrations

LC₅₀: >119.4 mg formulation/L 95% C.I.: N/A
NOAEC: 119.4 mg formulation/L Probit Slope: N/A
Endpoint(s) Affected: None

Results in terms of mean measured active ingredient (dicamba) concentrations

LC₅₀: >57.8 mg ai/L 95% C.I.: N/A
NOAEC: 57.8 mg ai/L Probit Slope: N/A
Endpoint(s) Affected: None

Results in terms of mean measured acid equivalent concentrations

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LC₅₀: >56.4 mg ae/L 95% C.I.: N/A
NOAEC: 56.4 mg ae/L Probit Slope: N/A
Endpoint(s) Affected: None

III. REFERENCES:

None